



**UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/406,269 | 09/24/99 | JIAO | J 48551 |

PETER F CORLESS
130 WATER STREET
BOSTON MA 02109

HM12/0109

EXAMINER

VOLLAND, J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1621

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DATE MAILED: 01/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/406,269

Applicant(s)
Jiao et al

Examiner
Jean F. Vollano

Group Art Unit
1621



☒ Responsive to communication(s) filed on Dec 7, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 and 12-63 is/are pending in the application.

Of the above, claim(s) 13-63 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10 and 12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The amendment filed 12/7/2000, paper no 9, has been entered. Claim 11 has been canceled . Claims 1-10 and 12-63 are pending.

Claims 13-63 are withdrawn from consideration as being drawn to non elected subject matter. The examiner notes that the face of the file has no reference to a provisional document being claimed . However, the declaration and the cross reference in the specification claims priority to provisional application 60/101887, filed 9/25/1998 and the file face is being changed to correct the error.

2. The examiner notes that the original Group II was chosen which included claims 1 (in part), claim 2, claim 3-4 and 5-12 (in part). The examiner agreed to include the inadvertently labeled second Group II which includes claim 2 as a method for treating a mammal with an effective amount of at least one TF blocking compound to treat a cardiovascular disease, a blood coagulation disorder , a cell proliferation disorder, postoperative complication, an immune disorder, atherosclerosis, inflammation or cancer. The claims from 1-10, and 12 are being examined to the extent that they read on the elected invention.

The examiner wants to remind the Applicant , as was stated in the last office action of 8/8/00 that the Independent claim 1 as it is given now reads on all of Group I which is not elected.

To hasten prosecution, Applicant should rewrite the claims to eliminate non elected subject

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matter from the claims. Applicant is also reminded that claims 13-63 are drawn to non elected subject matter.

3. The amendment has overcome the 35 U.S.C. 112, paragraph 1 rejection and the rejection is withdrawn.

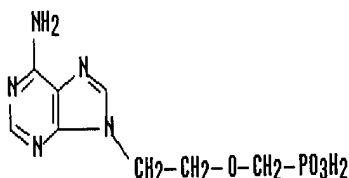
4. The amendment to the claims has overcome the objection to claims 6-12 as being improperly multiply dependent.

5. Applicant's arguments and the amendment has overcome most of the 35 U.S.C. 112 paragraph 2 rejection and the rejection is withdrawn with the exception of the rejection concerning the phrase "comprising at a least one phosphate group". Applicant argues that it is know that the phosphate group is a PO_3 group. The examiner agrees. The rejection was concerned with the word "comprising". The compound is just that one entity and not a mixture which comprises various moieties. The term is confusing as to whether the phosphate in part of the compound or is an additive with the word comprising. In a compound it would be clearer if the word contains (if it is enabled) or some other appropriate enabled word that denotes that the phosphate is part of the chemical structure and not an additive such as an phosphate salt etc. The term "comprising" also appears in claim 8-10 with bis phosphate or substituted carbocyclic aryl

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group etc. Therefore the part of the 35 U.S.C. 112, paragraph 2 rejection which includes claims 7-10 for the reasons cited above is maintained for reasons of record.

6. The rejection of claims 1-9 under 35 U.S.C. 102(b) as being anticipated by Chem abs 966 (CA:126:324966) is maintained for reasons of record. Applicant argues that the treatment suggested is HIV treatment the reference to cancer is just in the general statement of the art. Applicant has the method of use treatment for "an immune disorder". HIV would be considered



a disease which is an immune disorder. Therefore, even if the reference is not drawn to treatment of cancer it is drawn to treatment of an immune disorder and the rejection is maintained. It is noted that the compound being used in the reference is found below:

The compound fits the generic structure of Ar which is an optionally substituted heteroaryl group and CXY is ethylene with Het₁ being O and CX¹Y¹ not present and C(Z)_p being CH₂ (p=2).

The rejection is maintained.

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7. The amendment has limited the method of use claims to those compounds which are not found in US5854227. The rejection of claims 1-9 under 35 U.S.C. 102(e) as being anticipated by Hartmann et al (US5854227) is withdrawn.
8. The amendment has limited the method of use claims to those compounds which are not found in US5403829. The rejection of Claims 1-8 under 35 U.S.C. 102(b) as being anticipated by Lehtinen et al (US5403829) is withdrawn.
9. The amendment has limited the method of use claims to those compounds which are not found in Chem abs 356. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Chem abs 356 (CA:127:5356) is withdrawn.
10. The rejection of claims 1-10 and 12 under 35 U.S.C. 102(a) as being anticipated by Chem abs820 (CA:130:209820) is maintained for reasons of record.

In reference to the rejection Applicant argues that the compounds inhibit protein phosphatase I and because one compound is found to inhibit one unique enzyme has no bearing on the ability of the disclosed compound to inhibit a separate unrelated unique enzyme. Applicant argues that the 102(a) rejection is therefore improper.

The requirement of a 102 rejection is that all the limitations of the claims are disclosed or inherent. The compounds being used in Chem abs 820 fit within the structural definition of those

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being used in the instant invention. The utility of the compounds being used is for cardiovascular disorders which is the same utility being claimed by the instant invention. When one uses the drugs found in Chem abs 820 for cardiovascular diseases as taught by Chem abs 820 then the drugs being used would inherently fit the parameters of impacting tissue factor whether or not it is specifically taught in the prior art. A reference to a specific cancer drug used in treatment of cancer in one patent in which the patent does not give the specific interaction of the enzyme which is impacted on to treat cancer can be used in an anticipation rejection of the same specific cancer drug being used in the same treatment of cancer wherein the mechanism of action is known. The compounds being claimed as cardiovascular agents are disclosed in Chem abs 820 and the same utility as the instant invention is disclosed (cardiovascular agents). One using the known drug for the known treatment within active dosages would be inherently impacting on the TF factor as taught in the instant invention. Definition of a mechanism, in itself, does not confer patentable distinction to a known drug for a known utility. The examiner notes that although there is a provisional document being claimed as a priority document. The priority document teaches a generic Markush compound and some specific compounds contained in the Markush claim. However the priority document does not specifically disclose or teach toward some of the compounds specifically used by the prior art and as such the priority date is not given for the compounds or methods of use of these compounds which are not described or expressly suggested in provisional document.

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11. The amendment has limited the method of use claims to those compounds which are not found in Chem abs 249. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Chem abs 249 (CA:125:212249) is withdrawn.

12. The amendment has limited the method of use claims to those compounds which are not found in Chem abs 717. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Chem abs 717 (CA:124:45717) is withdrawn for reasons of record.

Claim Rejections - 35 U.S.C. § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and 3 have been amended to recite the limitation of a structure wherein the phrase "preferably " has been added. The phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr J F Vollano whose telephone number is (703) 305-4483. The examiner can normally be reached on Monday to Thursday from 6:30 to 5:00 .

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter , can be reached on (703)308-4532 . The official fax phone number for the

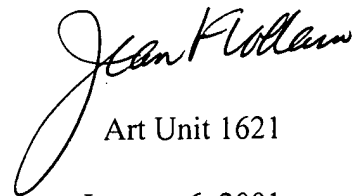
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organization where this application or proceeding is assigned is (703)308-4556. It should be noted that the examiner cannot immediately work on a fax sent to this number.

19. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

Jean F. Vollano

Primary Examiner

A handwritten signature in cursive script, appearing to read "Jean F. Vollano", written in black ink.

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January 6, 2001